REMARKS

Claims 7-9 and 20-25 were rejected. No claim has been allowed. Claims 7-9 and 20-25 are pending in the application.

Rejection Under 35 U.S.C. §§ 101 and 112, first paragraph

Claims 7-9 and 20-25 have been rejected as lacking either a credible, specific, and substantial utility or a well-established utility. According to the Office, the specification only indicates that IL-1δ "plays a role" in inflammation and does not predict the specific information provided by the references, *e.g.*, it is upregulated in psoriasis. The Office also asserts that the literature does not support the specification's more specific assertions of the effects of IL-1δ regarding chemoattractants, adhesion molecules, and fibroblast growth. Applicants traverse this rejection.

Applicants respectfully submit that the Office appears to have adopted an incorrect standard in maintaining the instant rejection. Specifically, the Office appears to be requiring a certain and exact evidence be disclosed for IL-1δ if the specification is to meet the utility requirement of §§ 101 and 112, *i.e.*, that the specification state that IL-1δ is upregulated in psoriasis. The MPEP defines a specific utility as one that is specific to the subject matter claimed, not a general utility that is applicable to the broad class of the invention. MPEP 2107.01(I). Applicants have met this standard. The specification identifies the cytokine, IL-1δ, as one that participates in a specific disease, inflammation. Not all cytokines function in inflammation, and therefore, this is not a general utility.

In essence, the Office appears to requiring proof beyond a reasonable doubt regarding the exact role of IL-1δ in inflammation and immune responses. However, Applicants note that only a reasonable correlation between the evidence and the asserted utility is required. As MPEP § 2107.03 (I) states:

> As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. [citations

> omitted] An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use as a matter of statistical certainty ... All that is required is a reasonable correlation. (emphasis included).

The specification provides a reasonable correlation between IL-1δ and inflammation. The specification discloses a specific biological activity for IL-1δ as a modulator of at least one specific disease condition: inflammation. *See, e.g.,* the specification, at page 31, lines 33-35 and at page 79, line 26 to page 80, line 11. The evidence supporting this utility lies in the structural and sequence similarities between IL-1δ and other family members. *See* specification at page 22, Table 3, at page 23, figure at bottom of page, and at page 40, lines 18-26 and lines 31-35. The members of the IL-1 family all possess a common β-barrel structure. IL-1δ has this common β-barrel structure. To date, all of the IL-1 family members that have been functionally characterized are involved in inflammation. Thus, the specification discloses that IL-1δ affects inflammatory responses. *See* specification, at page 31, lines 33-35.

The documentary evidence supports and validates the specification's stated utility for IL-1δ in inflammation. As discussed in the responses of record, both Debets *et al., J. Immunol.*, 167: 1440 (2001) and Kumar *et al., J. Biol. Chem.*, 275: 10308-14 (2000) provide definitive evidence in peer-reviewed publications that IL-1δ has a role in inflammation. This is demonstrated by the specific induction of inflammation-related cytokines, *i.e.*, IL-1β and TNF-α, *in vitro* as well as the expression of IL-1δ *in vivo* in recognized inflammatory diseases, *i.e.*, psoriasis. Thus, while the Office appears to acknowledge that inflammation is a specific disease state in the instant Action, it maintains its requirement that a specific type of inflammation must be identified for the utility requirement to be met. Applicants are not required to identify a specific type of inflammation or to predict the specific effects of IL-1δ in inflammation as asserted by the Office as there is no predetermined amount or character of evidence needed to support an asserted utility. Because the threshold of utility is not high under 35 U.S.C. § 101, an invention is useful if it is merely capable of providing some identifiable benefit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999) (*citing Brenner v. Manson*, 383 U.S. 519, 534 (1966)). In other words, only a

minimal utility is required. Therefore, the character and amount of evidence required is determined by what is claimed and whether it contravenes established scientific principle and belief. The character and amount of evidence disclosed in the specification and supported by documentary evidence is sufficient to meet the minimal utility standard set forth in 35 U.S.C. § 101. Simply stated, the utility of IL-1δ is expressly stated in the specification as a cytokine in inflammation, a specific disease, based on a recognized structural motif in the IL-1 family, and this utility is fully supported by the documentary evidence of record. This utility is substantial and credible to one of skill in the art in view of the disclosure and the documentary evidence of record.

Applicants respectfully submit that the Office's assertion that the literature does not support the specification's more specific assertions of the effects of IL-1δ is without merit. The list of effects cited by the Examiner represent a limited laundry list of the characteristics of inflammatory responses. The documentary evidence of record does not examine these characteristics. Nonetheless, the evidence of record is sufficiently probative regarding the expression of IL-1δ during inflammatory responses and diseases to meet the utility standard under 35 U.S.C. § 101.

Finally, the specification also sets forth other specific, substantial, and credible utilities for IL-1δ. Namely, the specification discloses IL-1δ's utility as a cytokine involved in viral infections and immunological disorders. *See* specification at page 78, line 33 to page 79, line 12. The post-filing references of record provide support for these specific, substantial, and credible utilities. First, Debets *et al.* demonstrates that IL-1δ acts as a specific and potent antagonist of IL-1ε. *See* Debets, at page 1443. Thus, one of ordinary skill in the art would appreciate that as an antagonist of an IL-1 family member, IL-1δ has utility in modulating the immune response mediated by IL-1ε. The specification discloses that IL-1ε and IL-1δ have related activities in immune functions. *See* specification, at page 31, lines 33-35. In this case, IL-1ε and IL-1δ regulate a single signaling cascade as agonist and antagonist, respectively. Second, Kumar *et al.* establishes IL-1ε is expressed *in vivo* in response to a viral infection (*i.e.*, herpes simplex virus). *See* Kumar, at page 10312-13 and Figures 4 and 5. In other words, IL-1ε functions similarly to other characterized IL-1 family members, namely IL-1α and IL-1β, in its involvement in viral response, while IL-1δ functions similarly to other characterized IL-1 family members, namely IL-1ra, as a modulator of a particular

IL-1 family member's function, *i.e.*, IL-1ε. Therefore, these references support an additional, disclosed utility for IL-1δ as a modulator of immune responses, particularly in anti-viral infections.

Taken together, the specification discloses IL-1δ as having a specific, substantial, and credible utility in inflammation, viral infections, and immune responses in general. Therefore, the utility requirement under §§ 101 and 112 has been met. Applicants respectfully submit that the rejections under 35 U.S.C. §§ 101 and 112, first paragraph are overcome and request the withdrawal of this rejection.

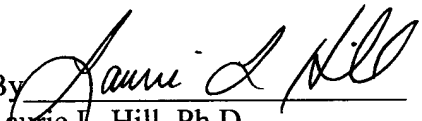
CONCLUSION

Applicants submit that the rejection under 35 U.S.C. §§ 101 and 112, first paragraph has been overcome by the above remarks. Early allowance of the remaining pending claims 7-9 and 20-25 is respectfully requested. If the Examiner thinks a telephonic conference would be helpful, please call the undersigned at (858) 720-7955 at your convenience.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000310. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 13, 2003

Respectfully submitted,

By 

Laurie L. Hill, Ph.D.
Registration No.: 51,804
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-7955